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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,542	10/24/2003	Masaharu Kojima	16422/005001	2304

7590 07/14/2005

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EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,542	KOJIMA ET AL.	
	Examiner	Art Unit	
	David A. Redding	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 12, 15, 17, 18 and 21 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 11, 13, 14 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment and arguments filed 4/18/2005. Applicants arguments regarding the prior art rejection of claims 10-12 are persuasive, however are now moot in view of the new grounds of rejection. Applicants arguments regarding the rejection of claims 1-7,15,17-20, are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,15,17,18,21 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,955,352 (Inoue et al.).

The patent discloses an instrument for chemical and microbiological tests which comprises a solid substrate (1), a sample absorbing portion (3), and a liquid absorbent body (2), see figures 1-3. Elements (1,2, and 4) constitute a container, the sample holding portions is considered to read on the claimed "at least one member" and is disclosed as being selected from "sponge-like porous substance" (col. 7, lines 28-46) or water-absorbing gels (col.7, lines 57-60). Reagents or anti-bacterial agents can be previously held in the sample holding portions (3) and a bacterial-containing culture medium can be added to the hollow region of the instrument (col.6, lines 51-67).

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Applicant's attention is specifically drawn to figures 4 and 5 which shows a sample absorbing region (11), a bared section within the sample absorbing region for the placement of a reagent (12) and the addition of a sample of cells and culture medium. The regions surrounding the elements (3) in figure 3 are also considered to constitute "bared" regions. The disclosure further discloses a method of forming the instrument shown in figures 3-5 which reads on claims 10,12,15,17, and 18 (col. 9, lines 20-39).

Further, applicants attention is drawn to the embodiment illustrated in figures 18-21 which includes a liquid- absorbing body (2) having hollow portions extending through the body. The body (2) can be made from sponge-like porous bodies or gels (col.11, lines 42-51). The body (2) sits atop the sample holding region (3) which has wells for holding drugs or medicine (see example # 6). A broth containing bacterial cells is added to the sample-holding portions which is considered to read on the claimed "culture medium components". The sample-holding portions (3) in figure 21 are considered to be cylindrical and read on claim 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 3,907,647 (Sanderson).

Figures 2 and 3 show a petri- dish containing a section (20) of agar and a bare bottom section (18). The reference is silent as to how this is made. However, one skilled in the art can deduce that the contents of the dish are formed by first placing the separator (17) in the bottom of the dish, covering a portion of the bottom surface, then pouring into the dish a solution containing culturing components (20) that can be gelatinized, and then gelatinizing the solution. Also, it is clear that after solidification the separator (17) could be removed as defined in claim 12. Accordingly the device of Sanders would obviously been made according to the steps claimed.

Response to Arguments

Applicants arguments center around the fact that the device of Inoue et al. *is used in a different manner* than that of the claimed invention. In response a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See

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In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Figures 1 thru 3 of Inoue et al. show a container having a member (x) which is disclosed to be a gel and a hollow region within the boundary of element 2 in which is poured a microbiological sample which would contain culture medium. The gel (2) would absorb some of the excess sample and inherently be capable of exchange with any solution placed within the interior.

Allowable Subject Matter

Claims 8,9,11,13,14,16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach or suggest the structural features of claims 8, 9,16 nor the process steps defined in claims 11, 13 and 14.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-9178. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David A Redding
Primary Examiner
Art Unit 1744

DAR